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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,396	10/20/2003	Michael H. Wigler	STRATAG.7C2DV2C1	3880
20995 7590 04/18/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER DUFFY, BRADLEY	
			ART UNIT 1643	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			NOTIFICATION DATE	DELIVERY MODE
3 MONTHS			04/18/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/18/2007.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/690,396	<b>Applicant(s)</b> WIGLER ET AL.	
	<b>Examiner</b> Brad Duffy	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed February 21, 2007, is acknowledged and has been entered. Claims 10 and 12 have been canceled. Claims 1, 2, 7-9, 11, and 17 have been amended.

2. Claims 1-9, 11 and 13-17 are pending in the application and currently under prosecution.

### ***Grounds of Objection and Rejection Withdrawn***

3. Unless specifically reiterated below, Applicant's amendment and/or arguments filed February 21, 2007 have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed August 14, 2006.

### ***Priority***

4. With regard to the issue of priority, Applicant has remarked that a petition to revive unintentionally abandoned Application No. 08/997,195 is still pending and the application has been marked "lost". Accordingly, until such a time that the prior filed application is located or reconstructed, and the petition has been decided, the issue of the effective filing date of the instant application, and whether it properly benefits under 35 U.S.C. § 120 by the earlier filing date of Application No. 08/997,195, cannot be determined.

Until such a time that the issue may be determined, the effective filing date of the instant application is to be considered November 12, 1999, as set forth in the previous office action.

### ***Grounds of Rejection Maintained***

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 1, 3-9, 11 and 13-17 under 35 U.S.C. 102(b) as being anticipated by Morrison et al (PNAS, 81:6851-6855, November 1984) (of record), is maintained.

At page 12 of the amendment filed February 21, 2007, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has argued that Morrison et al no longer anticipates the instant claims because claims 1 and 9 have been amended to recite isolated host cells producing an antibody or antibody fragment produced by a method comprising "selecting from a library DNA encoding an antibody ..." and that this method of producing host cells that produce antibodies was not disclosed by Morrison et al.

In response, it is noted that the claims are drafted in the product-by-process format and that the isolated host cells producing antibodies taught by Morrison et al are materially and structurally indistinguishable from the isolated host cells producing antibodies to which the claims are directed. Applicant is reminded that even though the product is defined by the process by which it is made, determination of patentability is based on the structure implied by that method. If a product that is linked in product-by-process format is the same as the product in the prior art, a claim reciting that product-by-process is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (FED. CIR. 1985). See also MPEP 2113.

Therefore, in this instance, claims 1 and 3-7 are directed to an isolated host cell producing an antibody or fragment thereof, which comprises a vector encoding an

antibody or fragment thereof, wherein the cell is a myeloma. Claims 8, 9, 11, and 13-17 are directed to an isolated host cell producing "antibodies" (i.e., antigen combining proteins), which comprise a vector encoding an antibody or fragment thereof, which produces an antibody or fragment thereof, wherein the cell is a myeloma.

As explained in the preceding Office action, Morrison et al teach isolated myeloma host cells producing antibodies (see entire document, e.g., page 6851, 1<sup>st</sup> column). Morrison et al. teaches the antibodies are encoded by expression vectors, which were introduced into the cells by protoplast fusion or calcium phosphate precipitation (page 6851, 2<sup>nd</sup> column). The vectors comprise DNA encoding polypeptides comprising the heavy chain variable region or the light chain variable region of the antibody (e.g., page 6851, 2<sup>nd</sup> column and Figure 1).

For these reasons, the Examiner disagrees with Applicant's contention that Morrison et al no longer anticipate the instant claims and the rejection of claims 1, 3-9, 11 and 13-17 under 35 U.S.C. 102(b), as being anticipated by Morrison et al, is maintained.

7. The rejection of claims 1, 2, 7, 8, 9, 11, and 17 under 35 U.S.C. 102(b), as being anticipated by anticipated by Skerra and Pluckthun (Science 240:1038-1041, 20 May 1988) (of record; cited by Applicant), is maintained<sup>1</sup>.

At page 12 of the amendment filed February 21, 2007, Applicant has traversed this ground of rejection.

Applicant has argued that the prokaryotic host cell producing an F<sub>v</sub> antibody fragment taught, as disclosed by Skerra and Pluckthun, is not a product made by a process comprising selecting DNA from a library and inserting said DNA into a framework antibody vector to produce an antibody fragment in host cells; and therefore Applicant has asserted the instantly claimed prokaryotic host cells producing antibodies are patentably distinct from those disclosed by the prior art.

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<sup>1</sup> Independent claims 1 and 9, from which the rejected claims 2 and 12 depend, were inadvertently omitted from this rejection in the Office action mailed August 14, 2006.

In response, as noted above, the claims are drafted in the product-by-process format and the isolated prokaryotic host cells producing an F<sub>v</sub> antibody fragment taught by Skerra and Pluckthun are materially and structurally indistinguishable from the isolated prokaryotic host cells producing antibody fragments to which the claims are directed.

Therefore, claims 1, 2, and 7 are directed to an isolated host cell producing an antibody or fragment thereof, which comprises a vector encoding an antibody or fragment thereof, wherein the cell is prokaryotic. Claims 8, 9, 11, and 17 are directed to an isolated host cell producing "antibodies" (i.e., antigen combining proteins), which comprise a vector encoding an antibody or fragment thereof, which produces an antibody or fragment thereof, wherein the cell is prokaryotic.

As explained in the preceding Office action, Skerra and Pluckthun teach isolated prokaryotic host cells producing F<sub>v</sub> fragments that combine with an antigen (see entire document, e.g., abstract), wherein the DNA encoding the antibody was inserted into a vector, which was introduced into the host cells (see abstract). Notably, the recitation in the instant claims that the DNA is in an "framework antibody" vector, or that the DNA is selected from a library does not distinguish the claimed product from the product disclosed by the prior art; i.e., the claimed host cells producing an antibody or antibody fragment are materially or structurally indistinguishable from those taught by Skerra and Pluckthun.

For these reasons, the Examiner disagrees with Applicant's contention that Skerra and Pluckthun no longer anticipate the instant claims and the rejection of claims 1-2 and 9 under 35 U.S.C. 102(b), as being anticipated by Skerra and Pluckthun, is maintained.

8. The rejection of claims 1, 2, 7, 8, 9, 11, and 17 under 35 U.S.C. 102(b) as being anticipated by anticipated by Better et al (Science 240:1041-1043, 20 May 1988) (of record), is maintained<sup>2</sup>.

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<sup>2</sup> See Footnoted #1.

At page 13 of the amendment filed February 21, 2007, Applicant has traversed this ground of rejection.

Applicant has argued that the prokaryotic host cells producing an Fab antibody fragment, as taught by Better et al, are not a product made by a process comprising selecting DNA from a library and inserting said DNA into a framework antibody vector to produce an antibody or antibody fragment in host cells; and therefore Applicant has asserted the instantly claimed prokaryotic host cells producing antibodies are patentably distinct from those disclosed by the prior art.

In response, as noted above, the claims are drafted in the product-by-process format, and the isolated prokaryotic host cells producing a Fab, as taught by Better et al, are materially and structurally indistinguishable from the isolated prokaryotic host cells producing antibodies or antibody fragments to which the claims are directed.

Claims 1, 2, and 7 are directed to an isolated host cell producing an antibody or fragment thereof, which comprises a vector encoding an antibody or fragment thereof, wherein the cell is prokaryotic. Claims 8, 9, 11, and 17 are directed to an isolated host cell producing "antibodies" (i.e., antigen combining proteins), which comprise a vector encoding an antibody or fragment thereof, which produces an antibody or fragment thereof, wherein the cell is prokaryotic.

Therefore, as explained in the preceding Office action, Better et al anticipate these claims because they teach isolated prokaryotic host cells producing Fab proteins (see entire document, e.g., abstract), wherein the DNA encoding the antibody is inserted into a vector and the vector is introduced into a host cell (see abstract). Notably, the recitation in the instant claims that the DNA is in an "framework antibody" vector, or that the DNA is selected from a library does not distinguish the claimed product from the product disclosed by the prior art; i.e., the claimed host cells producing an antibody or antibody fragment are materially or structurally indistinguishable from those taught by Better et al.

For these reasons, the Examiner disagrees with Applicant's contention that Better et al no longer anticipate the instant claim and the rejection of claims 1-2 and 9 under 35 U.S.C. 102(b) as being anticipated by Better et al, is maintained.

9. The rejection of claims 1-17 under 35 U.S.C. 102(b) as being anticipated by Wigler et al (U.S. Patent 5,780,225, published July 14, 1998 (of record), is maintained.

At page 13 of the amendment filed February 21, 2007, Applicant has remarked that U.S. Patent No. 5,780,225 will no longer be a prior art reference if the petition to revive Application 08/997,195 is granted.

Applicant's remarks have been carefully considered but, as explained above, until the petition is decided, this rejection will be maintained for the reasons set forth in the preceding Office action.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.



Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. The rejection of claims 1-17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent No. 6,635,424, is maintained for the reasons of record, as explained in the previous Office action.

At page 14 of the amendment filed February 21, 2007, Applicant has indicated that a terminal disclaimer will be filed when the obviousness-type double patenting is the only outstanding rejection.

This rejection will be maintained until it is appropriately resolved.

### ***Conclusion***

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1643

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,  
Brad Duffy  
571-272-9935

bd  
April 2, 2007

1 ✓  
STEPHEN KALLINGS  
PRIMARY EXAMINER  
ART UNIT 1643